



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/684,861      | 10/14/2003  | Bryon Merade         | CLDRA-001A          | 4794             |

7590 01/12/2006

MATTHEW A. NEWBOLES  
STETINA BRUNDA GARRED & BRUCKER  
Suite 250  
75 Enterprise  
Aliso Viejo, CA 92656

|          |
|----------|
| EXAMINER |
|----------|

LACYK, JOHN P

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3735

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/684,861 | <b>Applicant(s)</b><br>MERADE, BRYON |  |
|                              | <b>Examiner</b><br>John P. Lacyk     | <b>Art Unit</b><br>3735              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8, 10-12, 14, 16 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8, 10-12, 14, 16 and 18-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

1. Claim 6 is objected to because of the following informalities: In applicant's arguments, applicant states that claims 6 and 10 now define a first material to be "synthetic", however claim 6 states that the first material is a harvested segment of tissue not synthetic. Appropriate correction is required.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5-6, 8, 10-12, 14, 16, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobashi et al in view of Li and Willem et al.

Kobashi et al discloses the claimed device and method for treating incontinence and effectuate cystocele having an implant that is formed in a "T" shape having a sling portion and a bladder support portion, except for the device being made from both synthetic material and harvested tissue. Li and Willem et al teach that it is known to use slings for treating similar problems and teach that it is known to use a combination of both natural and synthetic materials. Therefore to make the device from both materials would have been obvious in view of the teachings of Li and Willem et al.

With respect to claims 12, 14, 16, as pointed out in applicant's specification (page 8, paragraphs 26-27), applicant states that the implantation procedures are well known, specifically that it is known to implant such devices by making a vaginal incision as well as by making an abdominal incision. Therefore to implant the device by any well known

method would have been obvious in view of applicant's own admission.

4. Claims 18-19, 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobashi et al in view of Li and Willem et al as applied to claims above, and further in view of Tripp et al.

Kobashi et al teaches a method of treating both cystocele and incontinence with a sling device. Tripp et al teaches that it is desirable and known to treat multiple conditions simultaneously, including systocele, rectocele, entercoeles and enterocystoceles.

Therefore a modification of Kobashi et al such that the device is used to treat any combination of conditions simultaneously would have been obvious in view of Tripp et al which shows that it is known to treat more than one condition at a time. With respect to the limitation of the device being "pre-fabricated" while this is considered to be directed to a step in the method of making the device and not further limiting in a method of treating the patient and/or implanting the device, Tripp et al further teaches (column 1, lines 15-18) that it is well known to provide "prefabricated" patches.

5. Applicant's arguments filed 10/17/05 have been fully considered but they are not persuasive. Applicant argues that there appears to be no suggestion in the references to construct the implant particularly comprising a sling portion from a synthetic material and a bladder support portion from a natural material. First, as now claimed in claim 1, the sling portion and bladder support portion do not include language limiting the portions to synthetic and natural material, respectively, all that is claimed is that they be

Art Unit: 3735

fabricated from a first and second material. Also the claims do not limit the sling portion and bladder support portion to being fabricated from only a first and second material, respectively. As discussed above, Li and Willem et al both teach that it is known to use slings for treating similar problems and teach that it is known to use a combination of both natural and synthetic materials. Since the claims are not limited to the sling portion being only a synthetic material and the bladder support portion being only a harvested segment of tissue, the teachings of Li and Willem et al as discussed, would teach the implant being made from a combination of synthetic and natural materials. Since the implant would be a combination of materials the sling portion would include a first material being a synthetic material and the bladder support would include a second material being a natural material or harvested tissue.

Applicant also argues that the implant is pre-fabricated and the Kobashi reference is directed to forming the T-shape during the operation. Firstly, it is improper to read a specific order of steps into method claims (see MPEP 2111.01). Further as pointed out in the above rejection Tripp et al clearly teaches that it is known to provide "prefabricated" patches. Also a reference is to be considered not only for what it expressly states, but for what it would reasonably have suggested to of ordinary skill in the art. Clearly it would have been obvious to one skilled in the art, in view of Tripp et al, to prefabricate the implant.

**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

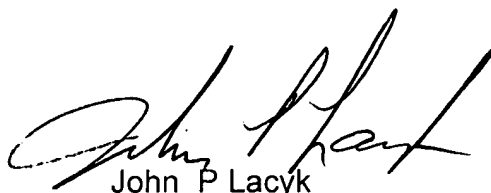
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571-272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P Lacyk  
Primary Examiner  
Art Unit 3735

J.P. Lacyk